California Medical Device Recall Information

Recall Name
Stryker Instruments Recalls Neptune Rover Waste Management Systems Due To Inadequate IFU Warnings for High Flow Suction

Recall Date	Product Description	Recalling Firm	Recall Reason
8/15/12	**Neptune Rover Waste Management Systems** • **Neptune 1 Bronze Rover** P/N 0700-007-000 • **Neptune 1 Gold Rover** (120V) P/N 0700-001-000 • **Neptune 1 Gold Rover Intl.** (230V) P/N 0700-002-000 • **Neptune 1 Silver Rover** (120V) P/N 0700-003-000 • **Neptune 2 Ultra Rover** (120V) Part Number (P/N) 0702-001-000 • **Neptune 2 Ultra Rover** (230V) P/N 0702-002-000	**Stryker Instruments** Kalamazoo, MI	*Potential for serious injury and death, due to inadequate Warnings and Instructions For Use.* *Also, the US FDA considers the **Neptune 1 Silver** and **Neptune 2** models to be Unapproved, New Devices subject to federal 510(k) clearance.*

Recall Class	Product Identification	Distribution	Affected Dates
I	**ALL serialized devices**	**CA**, nationwide, international	Manufactured: 01/11/01 - 08/01/12; Distributed: 03/26/01 - 08/07/12.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm325569.htm

http://www.stryker.com/stellent/groups/public/documents/adacct/147938.pdf